REMARKS

Claim 27-57 are currently pending in the application. Claims 27 and 44 have been amended. Claims 1-26 were previously canceled. Applicant respectfully requests reconsideration of the pending claims in view of the following remarks.

Claim Rejections – 35 U.S.C. § 103

The Examiner rejected Claims 27-57 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,117,829 ("Miller") in view of U.S. Patent Application Publication No. 2002/0080915 ("Frohlich") and further in view of U.S. Patent Application Publication No. 2001/0033682 ("Robar").

Miller does not disclose the subject matter of amended independent Claim 27. More specifically, Miller does not disclose a method for achieving a desired dose distribution comprising at least the following elements:

(a) obtaining at least one three-dimensional image from the patient in substantially a treatment position, the three-dimensional image including anatomical data and being used for volumetric dose calculations;

(b) comparing the at least one treatment planning image and the at least one three-dimensional image; and

(c) adjusting how the dose is received by the patient based on the comparison.

Rather, Miller discloses an alignment system for aligning a specified tissue volume of a patient with a charged-particle beam of a radiation therapy system. The patient is immobilized in a form-fitted pod, and reference radiographs and CT scan data are acquired. The patient is then allowed to return home. The CT scan data is analyzed and used to prepare a treatment plan for the patient. Once the treatment plan is finalized, the patient returns to the treatment location and repositioned within the pod. After the patient is positioned in the beam delivery system, an X-ray image is acquired that produces another radiograph, which is compared to the previously acquired radiographs (prior to treatment) to verify that the correct entry angle for the beam and correct patient position have been achieved.

The radiograph image acquired by the x-ray source while the patient is positioned in the beam delivery system are only two-dimensional; not three-dimensional as specified in the claim.

Frohlich does not cure the deficiencies of Miller. Frohlich does not disclose a method for achieving a desired dose distribution comprising at least the following elements:

(a) obtaining at least one three-dimensional image from the patient in substantially a treatment position, the three-dimensional image including anatomical data and being used for volumetric dose calculations;

(b) comparing the at least one treatment planning image and the at least one three-dimensional image; and

(c) adjusting how the dose is received by the patient based on the comparison.

Rather, Frohlich discloses a method of inverse planning for radiation therapy treatment including calculating a dose distribution for multiple treatment solutions and displaying the results for at least two of the treatment solutions for comparison by a treatment planner. The displaying of the two treatment solutions allows the treatment planner to select a desired one of the treatment solutions.

Frohlich focuses on the treatment planning portion of the process and does not disclose subject matter related to obtaining an image of a patient after the treatment planning process is completed and just prior to treatment delivery. Frohlich does not disclose "obtaining at least one three-dimensional image from the patient in substantially a treatment position, the three-dimensional image including anatomical data and being used for volumetric dose calculations," " comparing the at least one treatment planning image and the at least one three-dimensional image," and "adjusting how the dose is received by the patient based on the comparison."

Robar does not cure the deficiencies of Miller and Frohlich. Robar does not disclose a method for achieving a desired dose distribution comprising at least the following elements:

(a) obtaining at least one three-dimensional image from the patient in substantially a treatment position, the three-dimensional image including anatomical data and being used for volumetric dose calculations;

(b) comparing the at least one treatment planning image and the at least one three-dimensional image; and

(c) adjusting how the dose is received by the patient based on the comparison.

Rather, Robar discloses a post-treatment method of creating a three-dimensional data set based on phantom data. The method in Robar requires the delivery of treatment-level radiation to a phantom before the 3D data set can be generated. The method includes providing a plurality of radiation-sensitive films 12, which get exposed to a radiation field 17 produced by a radiosurgical system 16. The films 12 are held in a known position relative to the radiosurgery coordinate system during exposure so that the measured dose distribution can be coregistered with an intended dose distribution. The films may be processed in a suitable

processor 19 to provide a series of 2D images representing the integrated dose provided in different planes through the dose distribution being studied. Paragraph 34.

In addition, Robar does not disclose obtaining at least one three-dimensional image from the patient in substantially a treatment position, the three-dimensional image including anatomical data and being used for volumetric dose calculations. The 3D data set generated in Robar does not include anatomical data and cannot because the data is generated by irradiating a phantom. Because Robar does not obtain a 3D image prior to treatment delivery of at least one fraction, it cannot perform dose calculations, perform the claimed comparison of the specified image, or adjust how the dose is received by the patient prior to treatment delivery.

The Examiner indicates that "upon creation of the three-dimensional dose distribution created by Robar, this image may be "spatially co-registered in treatment planning software for comparison with an intended dose distribution," citing paragraph 45 and that "any deviations of the actual distribution from the intended dose distribution can thereby be identified before a radiosurgery treatment is delivered to a patient. The radiosurgery plan can be adjusted to correct these deviations," citing to paragraph 46.

Applicant respectfully points out that the 3D dose distribution created by Robar utilizes dose information that was delivered to a phantom (not a patient) and reconstructed from 2D images rather than a 3D image of the patient prior to treatment delivery. The comparison performed in Robar compares post-delivery data to pre-delivery data and cannot include any patient anatomical data, such as changes in the patient anatomy that may have occurred between the time of treatment planning and the date of treatment delivery. In contrast, the subject matter of Claim 27 specifies comparing pre-delivery data (e.g., data from the treatment plan) to other pre-delivery data (e.g., a 3D image taken prior to treatment delivery) both of which include patient anatomical data.

Furthermore, the three references cannot be combined. The method of Robar requires the delivery of radiation before the 3D dose distribution can be generated and then compared to pre-delivery data in order to adjust the plan if necessary, whereas Miller is more concerned with patient alignment with respect to the machine. Robar uses the data to compare actual dose distribution to an intended dose distribution to adjust a dose to be delivered, whereas Miller compares images to obtain proper registration of the patient. There is no indication that Miller is interested in dose distribution data as a way to align the patient prior to treatment delivery.

In addition, since the 3D data set is generated by irradiation of the phantom in Robar, it is apparent that Robar is concerned only about dose delivery from the radiosurgery machine (that is, only concerned about machine performance) and whether there will be any deviations

between the phantom dose delivery and the intended dose delivery to the patient. The 3D data set that gets generated in Robar does not include anatomical data, therefore Robar does not appear to consider patient anatomical changes with respect to the planning image and how the dose is going to be received by the patient due to those changes. Robar uses a phantom to determine if there will be any discrepancies in machine delivery performance without any reference to the patient and thus any dosimetric information derived from the 3D data set in Robar is based on assumptions about the patient, rather than being based on patient-specific information. As noted in paragraph 6 of Robar, it is necessary to be able to measure the actual volumetric dose distribution provided by a radiosurgery system apparatus so as to ensure that the apparatus is functioning properly and is producing the predicted dose distribution.

Because Miller and Robar are focused on very different aspects of treatment planning and preparation for treatment delivery, it would require impermissible hindsight to combine these two references as suggested by the Examiner.

For at least these reasons, Miller, Frohlich, and Robar do not disclose the subject matter of Claim 27. Accordingly, independent Claim 27 is allowable. Claims 28-43 depend from Claim 27 and are allowable for at least the reasons Claim 27 is allowable. Claims 28-43 may include additional patentable features not discussed herein.

Miller does not disclose the subject matter of amended independent Claim 44. More specifically, Miller does not disclose a method of delivering radiation therapy comprising at least the following elements:

(a) generating a plurality of radiation treatment plans for the patient based on the first image;

(b) acquiring a second image of the region of interest while the patient is in substantially a treatment position, the second image being three-dimensional and including anatomical data; and

(c) selecting one of the radiation treatment plans based on a position of the region of interest in the second image and dosimetric information in the second image.

As noted above, the radiograph image acquired by the x-ray source in Miller while the patient is positioned in the beam delivery system are only two-dimensional; not three-dimensional as specified in the claim.

Frohlich does not cure the deficiencies of Miller. Frohlich does not disclose a method of delivering radiation therapy comprising at least the following elements:

(b) acquiring a second image of the region of interest while the patient is in substantially a treatment position, the second image being three-dimensional and including anatomical data; and

(c) selecting one of the radiation treatment plans based on a position of the region of interest in the second image and dosimetric information in the second image.

As noted above, Frohlich focuses on the treatment planning portion of the process and does not disclose subject matter related to obtaining an image of a patient after the treatment planning process is completed and just prior to treatment delivery. Frohlich does not disclose "acquiring a second image of the region of interest while the patient is in substantially a treatment position, the second image being three-dimensional and including anatomical data" and "selecting one of the radiation treatment plans based on a position of the region of interest in the second image and dosimetric information in the second image."

Robar does not cure the deficiencies of Miller and Frohlich. Robar does not disclose a method of delivering radiation therapy comprising at least the following elements:

(a) generating a plurality of radiation treatment plans for the patient based on the first image;

(b) acquiring a second image of the region of interest while the patient is in substantially a treatment position, the second image being three-dimensional and including anatomical data; and

(c) selecting one of the radiation treatment plans based on a position of the region of interest in the second image and dosimetric information in the second image.

As noted above, Robar discloses a post-treatment method of creating a three-dimensional data set based on phantom data. The method in Robar requires the delivery of treatment-level radiation to a phantom before the 3D data set can be generated. The method includes providing a plurality of radiation-sensitive films 12, which get exposed to a radiation field 17 produced by a radiosurgical system 16. The films 12 are held in a known position relative to the radiosurgery coordinate system during exposure so that the measured dose distribution can be coregistered with an intended dose distribution. The films may be processed in a suitable processor 19 to provide a series of 2D images representing the integrated dose provided in different planes through the dose distribution being studied. Paragraph 34.

In addition, Robar does not disclose acquiring a second image of the region of interest while the patient is in substantially a treatment position, the second image being three-dimensional and including anatomical data. The 3D data set generated in Robar does not include anatomical data and cannot because the data is generated by irradiating a phantom.

Furthermore, the three references cannot be combined. The method of Robar requires the delivery of radiation before the 3D dose distribution can be generated and then compared to pre-delivery data in order to adjust the plan if necessary, whereas Miller is more concerned with patient alignment with respect to the machine. Robar uses the data to compare actual dose distribution to an intended dose distribution to adjust a dose to be delivered, whereas Miller compares images to obtain proper registration of the patient. There is no indication that Miller is interested in dose distribution data as a way to align the patient prior to treatment delivery.

In addition, since the 3D data set generated by irradiation of the phantom in Robar, it is apparent that Robar is concerned only about dose delivery from the radiosurgery machine (that is, only concerned about machine performance) and whether there will be any deviations between the phantom dose delivery and the intended dose delivery to the patient. The 3D data set that gets generated in Robar does not include anatomical data, therefore Robar does not appear to consider patient anatomical changes with respect to the planning image and how the dose is going to be received by the patient due to those changes. Robar uses a phantom to determine if there will be any discrepancies in machine delivery performance without any reference to the patient and thus any dosimetric information derived from the 3D data set in Robar is based on assumptions about the patient, rather than being based on patient-specific information. As noted in paragraph 6 of Robar, it is necessary to be able to measure the actual volumetric dose distribution provided by a radiosurgery system apparatus so as to ensure that the apparatus is functioning properly and is producing the predicted dose distribution.

Because Miller and Robar are focused on very different aspects of treatment planning and preparation for treatment delivery, it would require impermissible hindsight to combine these two references, as suggested by the Examiner.

For at least these reasons, Miller, Frohlich, and Robar do not disclose the subject matter of Claim 44. Accordingly, independent Claim 44 is allowable. Claims 45-49 depend from Claim 44 and are allowable for at least the reasons Claim 44 is allowable. Claims 45-49 may include additional patentable features not discussed herein.

Miller does not disclose the subject matter of independent Claim 50. More specifically, Miller does not disclose a method of delivering radiation therapy comprising at least the following elements:

(a) acquiring a second image of the patient substantially in a treatment position, the second image being three-dimensional and suitable for three-dimensional contouring;

(b) identifying a patient position with respect to a radiation delivery device based on dosimetric information and the contour.

The radiograph image acquired by the x-ray source while the patient is positioned in the beam delivery system is only two-dimensional; not three-dimensional as specified in the claim. In addition, a two-dimensional x-ray image is not suitable for three-dimensional contouring.

Frohlich does not cure the deficiencies of Miller. Frohlich does not disclose a method of delivering radiation therapy comprising at least the following elements:

(a) acquiring a second image of the patient substantially in a treatment position, the second image being three-dimensional and suitable for three-dimensional contouring, and

(b) identifying a patient position with respect to a radiation delivery device based on dosimetric information and the contour.

As noted above, Frohlich focuses on the treatment planning portion of the process and does not disclose subject matter related to obtaining an image of a patient after the treatment planning process is completed and just prior to treatment delivery. Frohlich does not disclose "acquiring a second image of the patient substantially in a treatment position, the second image being three-dimensional and suitable for three-dimensional contouring" and "identifying a patient position with respect to a radiation delivery device based on dosimetric information and the contour."

Robar does not cure the deficiencies of Miller and Frohlich. Robar does not disclose a method of delivering radiation therapy comprising at least the following elements:

(a) acquiring a second image of the patient substantially in a treatment position, the second image being three-dimensional and suitable for three-dimensional contouring, and

(b) identifying a patient position with respect to a radiation delivery device based on dosimetric information and the contour.

As noted above, Robar discloses a post-treatment method of creating a three-dimensional data set based on phantom data (not a patient). The method in Robar requires the delivery of treatment-level radiation to a phantom before the 3D data set can be generated. The method includes providing a plurality of radiation-sensitive films 12, which get exposed to a radiation field 17 produced by a radiosurgical system 16. The films 12 are held in a known position relative to the radiosurgery coordinate system during exposure so that the measured dose distribution can be coregistered with an intended dose distribution. The films may be processed in a suitable processor 19 to provide a series of 2D images representing the integrated dose provided in different planes through the dose distribution being studied. Paragraph 34.

In addition, Robar does not disclose acquiring a second image of the patient substantially in a treatment position, the second image being three-dimensional and suitable for three-dimensional contouring. There is no discussion in Robar regarding contouring.

Furthermore, the three references cannot be combined. The method of Robar requires the delivery of radiation before the 3D dose distribution can be generated and then compared to pre-delivery data in order to adjust the plan if necessary, whereas Miller is more concerned with patient alignment with respect to the machine. Robar uses the data to compare actual dose distribution to an intended dose distribution to adjust a dose to be delivered, whereas Miller compares images to obtain proper registration of the patient. There is no indication that Miller is interested in dose distribution data as a way to align the patient prior to treatment delivery.

In addition, since the 3D data set generated by irradiation of the phantom in Robar, it is apparent that Robar is concerned only about dose delivery from the radiosurgery machine (that is, only concerned about machine performance) and whether there will be any deviations between the phantom dose delivery and the intended dose delivery to the patient. The 3D data set that gets generated in Robar does not include anatomical data, therefore Robar does not appear to consider patient anatomical changes with respect to the planning image and how the dose is going to be received by the patient due to those changes. Robar uses a phantom to determine if there will be any discrepancies in machine delivery performance without any reference to the patient and thus any dosimetric information derived from the 3D data set in Robar is based on assumptions about the patient, rather than being based on patient-specific information. As noted in paragraph 6 of Robar, it is necessary to be able to measure the actual volumetric dose distribution provided by a radiosurgery system apparatus so as to ensure that the apparatus is functioning properly and is producing the predicted dose distribution.

Because Miller and Robar are focused on very different aspects of treatment planning and preparation for treatment delivery, it would require impermissible hindsight to combine these two references, as suggested by the Examiner.

For at least these reasons, Miller, Frohlich, and Robar do not disclose the subject matter of Claim 50. Accordingly, independent Claim 50 is allowable. Claims 51-54 depend from Claim 50 and are allowable for at least the reasons Claim 50 is allowable. Claims 51-54 may include additional patentable features not discussed herein.

CONCLUSION

In view of the foregoing, entry of this Amendment and allowance of the pending claims are respectfully requested. The undersigned is available for telephone consultation during normal business hours.

Respectfully submitted,

/julie a. haut/

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